No. 04-623

FILED
JUL 18 2005
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

ALBERTO GONZALES, ATTORNEY GENERAL, ET AL.,
Petitioners,

v.

STATE OF OREGON, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Does the Controlled Substances Act authorize the Attorney General to determine that prescribing a controlled substance for the purpose of enabling a mentally competent, terminally ill patient to secure assistance in dying is never within "the course of professional practice," even though such care is expressly authorized by state law?

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
INTEREST OF *AMICI CURIAE*	1
SUMMARY OF ARGUMENT	2
ARGUMENT	6
I. WRITING A PRESCRIPTION PURSUANT TO OREGON'S DEATH WITH DIGNITY ACT IS WITHIN "THE COURSE OF PROFESSIONAL PRACTICE" AND "THE LEGITIMATE PRACTICE OF MEDICINE"	6
A. Medical Practice Encompasses a Range of Humane Care	6
B. Many United States Physicians Today Consider Assistance in Hastening Death To Be Within "the Course of Professional Practice" in Some Cases	9
C. Many Competent Patients Consider Physician Assistance in Hastening Death To Be Within the Range of Care They Should Be Able To Obtain from Their Physicians	14
II. OREGON'S DEATH WITH DIGNITY ACT DOES NOT THREATEN THE PUBLIC HEALTH AND SAFETY	16
A. There Is No Evidence That the Oregon Statute Has Harmed the Public Health and Safety	16
B. The Oregon Statute Has Provided the Benefits Expected by Oregon Voters	17

TABLE OF CONTENTS—Continued

	Page
C. The Oregon Statute Has Also Brought Unexpected Benefits	19
D. Dangers That Exist Elsewhere Are Avoided in Oregon	20
III. THE CONTROLLED SUBSTANCES ACT APPROPRIATELY PRESERVES STATE AUTHORITY OVER MANY ASPECTS OF MEDICAL PRACTICE, INCLUDING THE USE OF CONTROLLED SUBSTANCES IN MEDICAL TREATMENT AT THE END OF LIFE	20
A. The Controlled Substances Act Aims To Curb Drug Trafficking, Preserving State Authority Except in Cases of a "Direct Conflict" with the Federal Act	20
B. Significant Aspects of the Medical Use of Controlled Substances Have Remained Free of Federal Control	23
C. The Attorney General Could Apply His Interpretation To Interfere With Many Other Forms of End-Of-Life Medical Care, Including Palliative Care and Refusals of Treatment	25
D. The Interpretive Rule Also Intrudes on Other State Authority	26
CONCLUSION	29

TABLE OF AUTHORITIES

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TABLE OF AUTHORITIES—Continued

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BRIEF FOR *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

INTEREST OF *AMICI CURIAE* [1]

Amici curiae are physicians, attorneys, and professors who address issues of medical ethics in their work. Their names, titles, and main institutional affiliations are listed in the Appendix. Each has studied the ethics of care for patients at the end of life. In the view of *amici*, the "course of professional practice" can include medical assistance for a mentally competent, terminally ill patient who seeks help in dying. *Amici*

[1] No one other than the named *amici* and their counsel wrote this brief in whole or in part, or made any monetary contribution to its preparation. The parties' written consents to the filing of this brief are being filed with the Clerk herewith.

also find the Attorney General's 2001 interpretive rule to be an inappropriate and legally insupportable assertion of federal authority over aspects of the practice of medicine that are the province of state law.

SUMMARY OF ARGUMENT

1. A physician's ongoing care for a mentally competent, terminally ill patient appropriately includes, if the patient so wishes and local law permits, assistance in enabling the patient to manage the time and manner of death. Such assistance is part of a continuum of humane medical care that begins with efforts to cure the patient and alleviate pain and suffering. If recovery becomes so unlikely that, in the patient's view, the burdens of continued attempts at a cure outweigh their benefits, then the physician redirects the course of treatment to meet the patient's wishes, while continuing to try to relieve pain and suffering. If, despite these efforts, the expected outcome is a physical or mental decline that the patient finds so repugnant, demeaning, or painful that an earlier death becomes preferable, then the physician may appropriately provide a patient who so requests with a drug to hasten death. The patient can then decide whether or not to ingest it. These forms of medical care have as their common core the physician's deep concern for the patient's well-being, informed by an understanding of the patient's convictions and most fundamental desires. In the views of many physicians practicing in the United States today and many of their patients, a physician's ability to provide assistance in hastening death is in some cases essential to effective end-of-life medical care.

Oregon's Death With Dignity Act enables patients to seek and willing physicians to provide assistance in dying after compliance with a number of procedural requirements. In providing such assistance, a physician usually prescribes a barbiturate, a Schedule II drug under the regulatory scheme established by the federal Controlled Substances Act. The

Act authorizes a physician licensed under it to prescribe controlled substances listed on Schedules II-V "in the course of professional practice." Accompanying regulations permit licensed physicians to prescribe these substances for any "legitimate medical purpose." These phrases are not defined, so their meanings must be determined by reference to the context in which they are used within the overall statutory scheme. Interpreted in this manner, the terms are plainly intended to draw a distinction between drug-trafficking and patient-centered medical care. Many physicians, scholars of bioethics, and patients alike today consider physician assistance in dying for mentally competent, terminally ill patients, as permitted by Oregon's Death With Dignity Act, to be within the meaning of the statutory and regulatory language of the Controlled Substances Act. In the view of *amici*, such assistance serves a legitimate medical purpose, and is a morally responsible way for the physician to respond to a competent patient's request.

Many physicians consider failure to provide assistance in dying to a patient who requests it to be abandonment of the patient just as death approaches. Continuing to aid a patient in need, indeed never abandoning a patient, is an important and long-standing principle of medical ethics. Depending on the circumstances, providing requested assistance in dying is an appropriate way for a physician to continue to address a patient's needs.

Notwithstanding the views of many in the medical profession and others expert in end-of-life issues, and without any serious effort to learn those views, in 2001 then-Attorney General Ashcroft issued an interpretive rule utilizing the language of the Controlled Substances Act and its accompanying regulations to claim authority to revoke a physician's license to prescribe controlled substances—essential to the practice of medicine—if the physician wrote a prescription pursuant to the Death With Dignity Act. In so doing, At-

torney General Ashcroft reversed the position of his predecessor, Attorney General Janet Reno. The Attorney General's rule is based on a belief that a physician's role is confined to curing or preventing disease or repairing injury. Pet. Brief at 18-19. This reflects a fundamental lack of understanding of contemporary medical practices and ethics.

The authority claimed by the Attorney General would enable him to revoke the licenses of physicians who prescribe controlled substances for other medical uses he considers inappropriate, including many practices currently in nationwide use. Among these are the use, at a dying patient's request, of sufficient controlled substances to relieve pain, even at the risk that the doses required may prove lethal. Another such practice is the use of controlled substances to reduce pain in dying patients who have refused further support from life-sustaining medical technology. An Attorney General who objects to such refusals could sharply curtail them by denying physicians the ability to prescribe controlled substances for relief of pain in patients who have made this choice. The analysis adopted by the Attorney General, if sustained, would empower him to interfere in a wide range of contemporary end-of-life medical practices.

2. The Death With Dignity Act has proved effective, providing comfort to many while not fostering abuse. The Attorney General does not contend otherwise. His claim that the Oregon statute imperils the public health and safety, thereby implicating the Controlled Substances Act, is wholly at odds with the historical record. The Oregon statute furthers rather than threatens the health and safety of the state's citizens.

The statute, as was intended, provides invaluable hope, enhanced palliative care, and relief from anxiety for those stricken with a terminal illness. It also benefits a much larger group of Oregon residents, who are comforted by the knowledge that should their circumstances ever lead them to desire

physician assistance in hastening death, they would be able to obtain it.

Speculation about possible intimidation of patients and abuse of the underprivileged has proved unfounded, according to the clear and reliable record created as a result of the statute's reporting requirements. Patients who seek prescriptions are on average better educated and more affluent than the average Oregonian. Use of hastened death has not spread in a way that might suggest lack of adequate controls; rather, the number of patients seeking prescriptions under the statute has been low—60 in 2004—and generally stable over the seven years the statute has been in effect. About one-third of the patients who obtain lethal prescriptions do not use them, confirming that the statute does not "kill" patients, but rather provides them with assistance in dying only if and when they choose it.

In addition, the statute protects against certain dangers, including underground and unregulated physician assistance in death, and painful acts of self-destruction by patients who feel trapped by their disease and compelled to kill themselves "before it is too late." In these circumstances, the statute serves to extend, not curtail, patients' lives. The Oregon statute is thus a reasonable medical and social response to the difficult end-of-life circumstances faced by some terminally ill patients. It is working as the people of Oregon intended and poses no threat to them.

3. Historically, many aspects of the practice of medicine have been regulated primarily by the states. The Controlled Substances Act allows federal regulation in one and only one limited respect: the prohibition of drug trafficking. This Act was adopted after efforts to control the scourge of drug abuse proved inconsistent and ineffectual in some parts of the country. Even with respect to substances governed by the Controlled Substances Act, however, the act preserves significant authority for the states. Because of the continuing

role of state law, wide variation regarding certain aspects of the use of controlled substances will survive no matter what the outcome of this case.

Indeed, the Controlled Substances Act expressly preserves state authority over controlled substances except in the event of a "direct conflict" with the federal act. Since the writing of a prescription under Oregon's Death with Dignity Act does not constitute drug trafficking and does not violate any express provision of the Controlled Substances Act, there is no "direct conflict" between the federal and state laws. The federal act by its terms does not contemplate, let alone authorize, the extraordinary exercise of federal power that would be required to preclude implementation of Oregon's Death With Dignity Act.

Continuing to permit the writing of prescriptions under Oregon's statute would not, as the Attorney General contends, subordinate his authority to the views of fifty states. Rather, the Attorney General's authority under the Controlled Substances Act is to enforce federal law as far as it goes, which is exclusively to prohibit drug trafficking. Beyond that point, the Act's "express conflict" provision ensures that other issues relating to the use of controlled substances in the "course of professional practice" and for "legitimate medical purpose[s]" remain, appropriately, the province of the states.

ARGUMENT

I. WRITING A PRESCRIPTION PURSUANT TO OREGON'S DEATH WITH DIGNITY ACT IS WITHIN "THE COURSE OF PROFESSIONAL PRACTICE" AND "THE LEGITIMATE PRACTICE OF MEDICINE"

A. Medical Practice Encompasses a Range of Humane Care

The practice of medicine is a morally committed enterprise that encompasses far more than serving as a "mechanic" of

bodily functions. The good physician provides the patient with comprehensive care, addressing the patient's psychological and emotional concerns as well as physical ailments. *Washington v. Glucksberg*, 521 U.S. 702, 779 (2001) (Souter, J., concurring). ("This idea of the physician as serving the whole person is a source of the high value traditionally placed on the medical relationship.")

Thus, the modern physician's role is not confined exclusively to curing or preventing disease or repairing injury. Physicians assist their patients in many different ways, including genetic counseling, dietary care, assistance in reproduction, and various forms of palliative care, including hospice care. Common to all of these forms of modern care are a concern for the alleviation of pain and suffering, emotional as well as physical, and a commitment to the patient's well-being. Various forms of medical assistance aimed at such relief are now taught in medical schools throughout the United States and have gained wide acceptance in the everyday practice of medicine.

Modern views about the range of ways in which physicians should appropriately care for patients have evolved over a period of decades. Palliative and hospice care, for example, were at first controversial, because in providing such care a physician forgoes further efforts at a cure. (Indeed, under the Attorney General's strained and narrow view, such care would not constitute legitimate practice, since it does not involve the prevention or cure of disease. *See* Pet. Brief at 19.) Today, however, a societal consensus has been reached and recognized in law that patients whose prospects for recovery are remote should be able to continue to obtain medical care to relieve their pain and suffering, both physical and emotional. Palliative and hospice care—although at their inception morally controversial—are now nearly universally approved. *See, e.g.*, T. Quill, B. Coombs Lee, and, S. Nunn, *Palliative Treatments of Last Resort: Choosing the Least*

Harmful Alternative, 132 Annals of Internal Medicine 488 (2000) ("Comprehensive palliative care . . . is the standard of care for the dying."); J. Rhymes, *Hospice Care in America*, 264 J. American Med. Ass'n 369 (1990) ("In the 16 years of its existence, hospice care in America has grown from an alternative health care movement to an accepted part of the American health care field.").

Similarly, a patient's right to refuse use of life-sustaining technology has gained acceptance over the past thirty years. Advances in medical knowledge and technology now allow some patients to be kept alive indefinitely, even though they are in a persistent vegetative state from which there is no realistic hope of recovery. Yet many patients do not wish their lives to be prolonged in this way. The law now empowers them to make enforceable declarations of a desire not to be given unwanted life-sustaining care. *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261 (1990); *Schiavo v. Schiavo*, No. 05-11628, slip op. at 9-14 (11th Cir. March 25, 2005), *available at* http://www.ca11.uscourts.gov/opinions/ops/200511628.pdf; *In re Quinlan*, 70 N.J. 10, 41 (1976).

For many terminally ill patients, palliative care and the ability to refuse treatment do not adequately address their concerns about their final days. They may face a protracted period of dying, devoid of even the simplest of pleasures, with a loss of functional capacity, possibly unremitting pain and suffering, and long hours of consciousness of the hopelessness of their condition. Many patients find this prospect unbearable. Increasingly, the medical profession and contemporary medical ethics have come to consider it appropriate to offer these patients a humane means of addressing their concerns. For some patients, this permits death with a dignity that they feel would otherwise be "denied . . . by their consciousness of dependency and helplessness as they [approach] death." *Glucksberg*, 521 U.S. at 779 (Souter, J.

concurring). In these circumstances, a physician's providing assistance in dying is not only within the legitimate bounds of medical practice, but a humane and moral response.

It would be more accurate if discussion of this medical practice were framed as "the right to die with dignity," or "hastening death," rather than as "physician-assisted suicide." When a mentally competent patient makes a choice to die during the final stages of a terminal illness there is no "suicide" in any conventional sense. The patient's act is utterly unlike the cutting short, under the influence of depression or mental confusion, of a potentially long and rewarding life. The ingestion of a controlled substance in order to accelerate death may spare the terminally ill patient much suffering, both physical pain and the anguish that, for some, accompanies helplessness and dependence. Reflecting this distinction, the Oregon statute explicitly provides that actions taken pursuant to the statute "shall not, for any purpose, constitute suicide, assisted suicide, mercy killing or homicide, under the law." Or. Rev. Stat. 127.880 (2003).

B. Many United States Physicians Today Consider Assistance in Hastening Death To Be Within "the Course of Professional Practice" in Some Cases

The Controlled Substances Act requires that controlled substances be prescribed only "in the course of professional practice." 21 U.S.C. 801-971 (2004) ("CSA" or "the Act") at 21 U.S.C. 802(21). The accompanying regulations contain a similar standard, requiring that any prescription for a controlled substance be for a "legitimate medical purpose." 21 C.F.R. 1306.04(a) (2004). These terms are not defined in either the CSA or its associated regulations and so must be read in their context "with a view to their place in the overall statutory scheme." *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989). *Accord, FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000). The CSA was

intended to prevent drug trafficking and drug abuse, and the terms in question were designed to distinguish the physician who is caring for patients from the physician who is acting as a "pusher," that is a person who is using his license as a physician to make a profit by diverting controlled substances into drug trafficking. *United States v. Moore*, 423 U.S. 122, 142-43 (1975). In determining what conduct constitutes drug-trafficking under the CSA, this Court has distinguished that conduct from "a standard of medical practice generally recognized and accepted in the United States." *Id.* at 139.

Courts have relied on experts to define that standard. As long as the physician is providing care that meets "a standard of medical practice" generally recognized and accepted by the medical community, then the physician's prescribing of controlled substances is permissible under the CSA. *See, e.g., U.S. v. Tran Trong Cuong, M.D.*, 18 F.3d 1132, 1137-39 (4th Cir. 1994) ("[t]he testimony of these witnesses together with that of the government's expert was sufficient to prove the essential elements of the charges"); *United States v. Moore*, 505 F.2d 426 (D.C. Cir. 1974) (MacKinnon, J., dissenting), *reversed, Moore*, 423 U.S. 122 ("[a]s established by expert medical testimony at trial, . . . Dr. Moore's detoxification treatment was not consistent with any method . . . accepted by the medical profession in this country") (internal quotation marks omitted).

A recent survey finds that a majority—57%—of physicians practicing in the United States today consider it ethical to assist a terminally ill, mentally competent patient who has made a considered choice to terminate life in order to avoid unbearable suffering, as the Oregon statute permits. Or. Rev. Stat. 127.800-995 (2003) ("Oregon statute"), *available at* http://www.leg.state.or.us/ors/127.html; Poll conducted by Louis Finkelstein Institute for Social and Religious Research and HCD Research, *Physician-Assisted Suicide Survey*, (March 2005), *available at* http://www.jtsa.edu/research/finkelstein/

surveys/pas.shtml. Other studies have found similar support among a plurality of physicians. K. Novielli, *Correlates of Physicians' Endorsement of the Legalization of Physician-assisted Suicide*, 75 Academic Medicine S53 (2000).

The pages of respected medical journals also demonstrate that a significant number of physicians today consider assistance in dying to be squarely within the bounds of legitimate medical practice, whether the patient's motivation is the alleviation of physical pain or relief from existential suffering. *See, e.g.*, T. Quill and C. Cassel, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, 138 Annals of Internal Medicine 208 (2003) (summarizing views of physicians and observing that many professional medical organizations do not view assisted suicide or hastening death as inappropriate); T. Quill, B. Lo, and D. Brock, *Palliative Options of Last Resort: A Comparison of Voluntarily Stopping Eating and Drinking, Terminal Sedation, Physician-Assisted Suicide and Voluntary Active Euthanasia*, 278 J. American Med. Ass'n 2099 (1997) (discussing end-of-life options and contending that, in certain circumstances, assistance in hastening death is appropriate medical care); F. Miller, *et al.*, *Regulating Physician-Assisted Death*, 331 N. Eng. J. Med. 119 (1994) (contending that assistance in dying is a medical practice, albeit one reserved for extraordinary circumstances).

The very authorities cited by the Attorney General demonstrate that the unanimity he claims to find among medical professionals does not exist. For example, the Attorney General says that "[n]umerous health care experts have . . . agreed" that physician assistance in hastening death is never a legitimate medical practice, citing the report of the New York State Task Force on Life and the Law, *When Death Is Sought: Assisted Suicide and Euthanasia in the Medical Context* (May 1994) ("New York Task Force Report"). Pet. Brief at 23. The Attorney General fails to mention that although the Task

Force recommended against legalization (principally on the basis of speculative fears that have not been realized in Oregon), the report also made clear that some Task Force members did not "share the conclusion that assisted suicide is inherently unethical or incompatible with medical practice." New York Task Force Report at 140, *available at* http://www.health.state.ny.us/nysdoh/provider/death.htm. "In fact, they believe that in appropriate circumstances, this assistance would manifest a physician's commitment and duty to his or her patient." *Id.*

As important as physicians' stated opinions is their actual practice. While statistics are necessarily elusive since assistance in hastening death is illegal in most states, the evidence available indicates that the practice has existed in secret in the United States for some time. *See, e.g.,* D. E. Meier, *et al., A National Survey of Physician-Assisted Suicide and Euthanasia in the United States*, 338 New Eng. J. Med. 1193 (1998) (11% of physicians polled reported that under current legal constraints, there are circumstances in which they would prescribe a medication for a competent patient to use with the primary intention of ending his or her life); L. R. Slome, *et al., Physician-Assisted Suicide and Patients with Human Immunodeficiency Virus Disease*, 336 N. Eng. J. Med. 417 (1997) (53% of 117 Bay area physicians specializing in the care of patients with AIDS indicated that they had acceded at least once to a request to hasten death); E. Emanuel, *et al., Euthanasia and Physician-assisted Suicide: Attitudes and Experiences of Oncology Patients, Oncologists, and the Public*, 347 Lancet 1805 (1996) (in one study, half of oncologists surveyed had received a request for assisted death, and 14% had complied).

In arguing that assistance in hastening death is outside the scope of legitimate medical practice, some point to the Hippocratic Oath, which prohibits the giving of a "deadly drug." Ancient Medicine: Selected Papers of Ludwig Edelstein 6

(Owsei Temkin and C. L. Temkin eds. 1987). Their views are informed more by tradition, however, than by analysis. Moreover, it is a tradition with questionable historical foundations and little viability today. This provision in the Oath, like many of its other provisions, did not reflect accepted medical practice in ancient Greek city-states, where, upon request, a physician would provide a lethal drug for a suffering patient he could not cure. *Id.* at 11-13. More importantly, today the Hippocratic Oath is administered at only one U.S. medical school in its original form; its prohibitions on many practices integral to contemporary medicine have led to its abandonment or replacement at all other U.S. schools. Moreover, only 6 of 122 U.S. medical schools administer an oath that would prohibit physician assistance in hastening death. *See, e.g.,* A. C. Kao and K. P. Parsi, *Content Analyses of Oaths Administered at U. S. Medical Schools in 2000*, 79 Academic Medicine 882 (2004).

The Attorney General's contention that physician assistance in dying is uniformly condemned by the medical profession under all circumstances is demonstrably incorrect. And while admittedly there is some disagreement in the medical and bioethics communities about physician assistance in hastening death, this adduces nothing: many practices about which there is disagreement among professionals are clearly within "the course of professional practice."

The cited polls, the views of physicians and others as expressed in respected medical publications, and reports of actual physician practice demonstrate that assistance in hastening death is accepted by a substantial percentage of physicians and scholars of bioethics as legitimate and humane. Thus, the practice is within "the course of professional practice," and serves a "legitimate medical purpose," as required by the Controlled Substances Act and its accompanying regulations. 21 U.S.C. 802(21); 21 C.F.R. 1306.04 (a). The Attorney General's strained interpretation of this language,

which leads him to conclude that prescribing a controlled substance to provide a patient with the means of hastening death can *never* constitute a legitimate medical practice, ignores this solid evidence.

C. Many Competent Patients Consider Physician Assistance in Hastening Death to be Within the Range of Care They Should Be Able to Obtain from Their Physicians

Coinciding with the evolution of modern medical practice has been increased respect by physicians for the patient's autonomy. Modern medical practice requires a physician to listen carefully to the patient's needs and desires and be skilled in imparting to the patient the medical options available. No longer do patients simply accept a treatment prescribed by their doctors, but instead they participate, based on their doctors' advice about medical consequences, in selecting, planning, and conducting their own medical care, and ultimately in assuming responsibility for implementing it. This development has been particularly pronounced with respect to end-of-life care.

Thirty years ago, before the seminal decision in *Quinlan*, there was no generally recognized legal right to refuse or direct the withdrawal of life-sustaining treatment. *See Cruzan*, 497 U.S. at 270; *Quinlan*, 70 N.J. at 41. No established public policy set the contours of the decision-making rights of seriously ill or injured patients. The physicians participating in *Quinlan* maintained that such judgments are exclusively medical in nature and that withdrawal of life-sustaining treatment violated accepted ethical standards. *Quinlan* reshaped the law, medicine, and medical ethics with its holding that the patient's judgment must prevail over the physician's with respect to certain decisions at the end of the patient's life.

By providing a legal means of realizing an option long sought and sometimes obtained in the shadows by the terminally ill, the Oregon statute reflects this increased respect for patient autonomy. For some patients, given their symptoms, the imminence of their death, its likely form, and their most deeply held values and convictions, the prospect of survival in a wholly dependent or vegetative state or in unbearable and unrelievable physical pain or suffering is, literally, worse than death. For them, a physician's dispensing of a controlled substance to make their death tolerable constitutes fulfillment of the physician's moral duty to attend to their needs.

The percentage of potential patients and their families who consider assistance in dying appropriate for the terminally ill who desire it now constitutes a sizeable majority. In 2003, members of the public were asked, "When a person has a disease that cannot be cured, do you think physicians should be allowed to end that patient's life by some painless means, if the patient requests it?" Seventy-two percent of those polled answered "Yes." K. Jost, *Right to Die*, 15 CQ Researcher No. 18 at 428 (2005), *citing* polls by Public Agenda and Gallup Organization conducted in January 1950 and May 2003.[2]

It is inaccurate to dismiss patients who desire assistance in dying as merely suffering from depression. As Justice Souter wrote in his concurrence in *Glucksberg*,

> The patients here sought not only an end to pain (which they might have had, although perhaps at the price of stupor) but an end to their short remaining lives with a dignity that they believed would be denied them by powerful pain medication . . . . In that period when the end is imminent, they said, the decision to end life is closest to decisions that are generally accepted as proper instances of exercising autonomy over one's own

[2] Notably, the survey question describes a process in which, in sharp contrast to the more restrictive Oregon law, the physician may administer a lethal dose of a controlled substance. Under Oregon law, the patient must ingest the substance.

body, . . . instances in which the help of physicians is accepted as falling within the traditional norm.

Glucksberg, 521 U.S. at 779. *See also Glucksberg*, 521 U.S. at 742 (Stevens, J., concurring) (noting the terminally ill patient's "basic interest in controlling the manner and timing of her death").

II. OREGON'S DEATH WITH DIGNITY ACT DOES NOT THREATEN THE PUBLIC HEALTH AND SAFETY

A. There is No Evidence that the Oregon Statute Has Harmed the Public Health and Safety

The Oregon statute was adopted by direct vote of the people of the state in 1994 and again in 1997. Or. Rev. Stat. 127.800 *et seq.* (2003). It has now been in effect for more than seven years, and because of its reporting requirements, detailed information is now available about its implementation. Or. Rev. Stat. 127.855 (2003). The evidence is uniformly favorable. Or. Dep't of Human Services, Seventh Annual Report on Oregon's Death With Dignity Act (2005), *available at* http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf ("2004 Report"). Speculative fears about abuse have not materialized, the expected benefits have been achieved, and unanticipated advantages have been realized as well. There is no evidentiary basis for invoking the Controlled Substances Act, 21 U.S.C. 801-971, as the Attorney General seeks to do, on the grounds that the Death With Dignity Act imperils the public health and safety of the people of Oregon. *See* Memorandum for the Attorney General from Office of Legal Counsel, Department of Justice (June 27, 2001), Pet. App. 106a. ("OLC Memorandum").

Importantly, there is no evidence that any patient has died other than in accordance with his or her own wishes. Notably, many patients who obtain a prescription for a lethal dose of a controlled substance choose never to ingest it. In 2004

one-fifth of the 60 patients who obtained prescriptions died from natural causes, and another one-fifth were still alive at year's end. 2004 Report at 12. Moreover, many patients seriously consider obtaining a prescription for a lethal dose but then never choose to do so. 2004 Report at 16. Under the statute, mentally competent, terminally ill patients remain securely in control of decision-making about their lives.

Initial concern that the statute's restrictions might be loosened in practice has not proved warranted. Use of the statute has been limited, and levels of use have remained stable. Only 208 people in the last seven years have obtained assistance in dying. The 37 deaths attributable to hastened death in 2004 amount to about one in 800 deaths among Oregonians. 2004 Report at 16. Nor has hastened death been used primarily by individuals who might be thought vulnerable to intimidation or abuse. Those choosing assisted death had on average a higher level of education and better medical coverage than terminally ill Oregonians who did not obtain assistance in dying. 2004 Report, Tables 2 and 4. The elderly, women, people with disabilities, and members of disadvantaged racial minorities have not been disproportionately affected. Only 3% of those who obtained assistance in dying were reported to have expressed concern about the financial costs of treatment. 2004 Report, Table 4. There is no evidence of influence by greedy relatives, callous physicians, or profit-minded health insurers. In short, there is no evidence that the Death With Dignity Act has been a dangerous policy choice. To the contrary, it has facilitated autonomous decision-making by mentally competent, terminally ill patients at a time when they have little other control over their lives.

B. The Oregon Statute Has Provided the Benefits Expected by Oregon Voters

This favorable record is in part the result of the procedural protections imposed by the Oregon statute. In order for a

prescription for a lethal dose to be written: (1) the patient must be a capable adult resident of Oregon diagnosed with a terminal illness that will likely lead to death within six months, Or. Rev. Stat. 127.800(12), 127.805 (2003); (2) the patient must make two oral requests, separated by at least fifteen days, *id*. at 127.840, and one written request, signed in the presence of two witnesses, *id*. at 127.810; (3) the prescribing physician and a consulting physician must confirm the terminal diagnosis and prognosis and determine that the patient is capable, *id*. at 127.815(1)(a), 127.820; (4) the prescribing physician must inform the patient of feasible alternatives to hastened death, including comfort care, hospice care, and pain control, *id.* at 127.815(1)(c)(E); (5) satisfaction of the foregoing requirements and a report of relevant data must be entered on the patient's medical record, *id.* at 127.855; and (6) the prescribing physician must request (but may not require) that the patient notify his or her next of kin of the prescription request. *Id.* 127.835. If either the prescribing or the consulting physician believes that the patient lacks the capacity to make a rational choice, the patient must be referred for counseling. *Id.* at 127.825. The statute protects physicians from criminal liability only if they have complied with all of its requirements. *Id*. at 127.890 (4).

Almost all in Oregon who have sought prescriptions under the Death With Dignity Act cited emotional suffering arising from the loss of control over the circumstances of their lives as a major reason for their decision. 2004 Report, Table 4. Others sought to avoid loss of physical capacity or of their sense of dignity. *Id*. Some feared intolerable pain not controllable by medication. *Id*. All of these concerns must be acknowledged as serious and deeply felt. *See Cruzan*, 497 U.S. at 292 (1990) (Scalia, J., concurring) (noting "the constantly increasing power of science to keep the human body alive for longer than any reasonable person would want to inhabit it"). For these Oregon residents, the Death With Dignity Act affords a final measure of self-determination that

their illnesses might otherwise have denied them. It enables them to end their lives in a manner they consider humane and dignified. Or. Rev. Stat. 127.805 (2003).

At the same time, the statute comforts many who never seek to utilize it, but might have done so in different circumstances. It provides all of the citizens of Oregon with the knowledge that should a terminal illness place them in a condition they find intolerable, an escape would be available.

C. The Oregon Statute Has Also Brought Unexpected Benefits

The Death With Dignity Act has produced unexpected benefits as well. In a survey of Oregon physicians concerning their attitudes toward and experiences with end-of-life care since passage of the statute, more than 75% of physicians interviewed reported that "they had made efforts to improve their knowledge of the use of pain medications in the terminally ill" and "their confidence in the prescribing of pain medications had improved." L. Ganzini, *et al., Oregon Physicians' Attitudes About and Experiences With End-of-life Care Since Passage of the Oregon Death with Dignity Act*, 285 J. American Med. Ass'n 2363, 2365-66 (2001). Almost 70% of physicians also "reported that they sought to improve their recognition of psychiatric disorders, such as depression." *Id*. at 2365. Finally, referrals to hospice care have increased dramatically since passage of the statute. M. McCauley, *Taking a Look at 2004* at 2, Table: Hospice Penetration Rates, (Or. Hospice Ass'n Newsletter 2005) *available at* http://www.oregonhospice.org/graphics/pdfs/2004newsletter0305.pdf (showing that hospice usage in Oregon nearly doubled from 1994 to 2003 and is well above the national average). The Oregon statute produces these results by focusing attention on the physical and mental suffering that accompanies terminal illness and thus by encouraging efforts to better alleviate these burdens.

D. Dangers That Exist Elsewhere Are Avoided in Oregon

While only a small number of terminally ill patients formally request a lethal prescription and even fewer ultimately ingest one, studies show that many more terminally ill patients seriously consider seeking assistance in dying. E. Emmanuel, *et al.*, *Attitudes and Desires Related to Euthanasia and Physician-assisted Suicide Among Terminally Ill Patients and Their Caregivers*, 284 J. American Med. Ass'n 2460-68 (2000). Those who lack the legal option to seek assistance in dying may seek assistance illegally, without the safeguards the Oregon statute affords that state's residents. Other such patients will resort to violent self-help. The Oregon statute regulates assistance in dying and subjects it to scrutiny through extensive record-keeping requirements.

The Controlled Substances Act provides that the public health and safety is one factor for the Attorney General to consider in determining whether registration of a particular physician is consistent with the public interest. 21 U.S.C. 823(a)(6). The evidence establishes that the Death With Dignity Act has promoted, not harmed, the health and safety of Oregon residents.

III. THE CONTROLLED SUBSTANCES ACT APPROPRIATELY PRESERVES STATE AUTHORITY OVER MANY ASPECTS OF MEDICAL PRACTICE, INCLUDING THE USE OF CONTROLLED SUBSTANCES IN MEDICAL TREATMENT AT THE END OF LIFE

A. The Controlled Substances Act Aims to Curb Drug Trafficking, Preserving State Authority Except in Cases of a "Direct Conflict" with the Federal Act

States have traditionally held primary responsibility for many aspects of the regulation of medical care. *See, e.g,*

Bowen v. American Hosp. Ass'n, 476 U.S. 610, 645 (1986) (regarding proposed federal regulations governing medical care of newborns, "[t]he propriety of the exertion of . . . [federal] authority must be tested by its relation to the purpose of the [statutory] grant and with suitable regard to the principle that whenever the federal power is exerted within what would otherwise be the domain of state power, the justification of the exercise of the federal power must clearly appear"). When some states proved less than effective in deterring drug trafficking, however, Congress stepped in and, by enactment of the Controlled Substances Act, sought to augment with federal support existing state efforts to keep drugs out of illicit channels of distribution. At the time it passed the federal act, Congress confronted a mosaic of existing state provisions and practices relating to these drugs. It decided to leave most of that state structure in place, 21 U.S.C. 903, and to enhance, not replace, state law. Consistent with its limited goals, Congress expressly limited the new authority it extended to the federal government by recognizing and approving the states' continuing role. *Id.*

That the CSA was intended and designed to deter drug trafficking has been recognized by this Court and others. *See, e.g., Moore*, 423 U.S. at 139; *United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975). In *Moore*, the Court interpreted the statutory language, "in the course of professional practice," and distinguished between a physician who dispensed drugs "within . . . legitimate channels" and one who "sold drugs, not for legitimate purposes, but primarily for the profits to be derived therefrom." *Moore,* 423 U.S. at 135, *citing* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4575 (internal quotations marks omitted). Medical practice under the Death With Dignity Act does not involve trafficking or the distribution of drugs "primarily for . . . profit[]." *Id.*

The Attorney General relies on the statutory and regulatory provisions that permit him to revoke a physician's license to

prescribe controlled substances if the physician has prescribed such substances for a reason other than "in the course of professional practice" or for other than a "legitimate medical purpose." 21 U.S.C. 802(21); C.F.R. 1306.04. Since without such prescription-writing authority a physician as a practical matter cannot practice medicine, and since controlled substances, particularly barbiturates, are what physicians find medically responsible to provide to patients who choose to hasten death, 2004 Report at 14, the Attorney General's interpretive rule would effectively nullify the Oregon law. Interpretive Rule, AG Order No. 2534-2001 (Nov. 9, 2001), Pet. App. 100a. Yet the CSA provides that:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a *positive conflict* between that provision of this sub-chapter and that State law so that the two cannot consistently stand together.

21 U.S.C. 903 (emphasis added).

The CSA, which addresses the diversion of drugs into illicit channels of distribution, does not by its terms prohibit the use of controlled substances in the hastening of death. The Death With Dignity Act does not by its terms authorize or foster any form of drug trafficking. The two statutes can stand together without tension, much less conflict. Congress provided that the CSA should be interpreted to avoid unnecessary collision with state law. In clear violation of this provision, the Attorney General has contrived a results-driven analysis that seeks to create a conflict where none exists. His interpretive rule is in direct contravention of the "positive conflict" provision of the CSA.

B. Significant Aspects of the Medical Use of Controlled Substances Have Remained Free of Federal Control

The CSA's express deference to state regulation of aspects of medical practice is reflected in several ways. For example, once the Attorney General or his surrogate has identified at least one legitimate medical use of a substance, a physician is free to prescribe the substance for any medical purpose. *See* J. Beck & E. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug Law Journal 71, 72 (1998) ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize.").

In addition, the continuing role of the states results in considerable diversity. While no state purports to authorize conduct that would violate federal law, at least 36 states have exercised authority over important aspects of the use of controlled substances in patient care by enacting statutes or issuing regulations or guidelines. Some states encourage pain management. *See, e.g.*, Or. Rev. Stat. 677.474 (2003), *available at* http://www.leg.state.or.us/ors/677.html ("Notwithstanding any other provision of this chapter, a physician licensed under this chapter may prescribe or administer controlled substances to a person in the course of the physician's treatment of that person for a diagnosed condition causing intractable pain."). Other states have adopted model guidelines issued in 1998 by the Federation of State Medical Boards of the United States that are more restrictive, at least in tone. *See, e.g.*, Nev. Admin. Code 630.187 (2004), *available at* http://www.leg.state.nv.us/NAC/NAC-630.html#NAC630Sec187, adopting *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, available at* http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/model_pain_guidelines.htm ("the physician

should adjust drug therapy to the individual medical needs of each patient"). Other states specifically address end-of-life care and expressly authorize the physician to consider the patient's personal dignity as well as comfort. *See, e.g.*, Me. R. 02-373-011, § 3 ("The Principles of End of Life Pain Therapy: In the instance of chronic end of life pain, a treatment plan which addresses the goals of comfort and personal dignity, developed at the time of original diagnosis, is sufficient. . . ."), *available at* ftp://ftp.maine.gov/pub/sos/cec/rcn/apa/02/373/373c011.doc. *See generally*, St. Louis University and American Society of Law, Medicine & Ethics, State Pain Policies [and] Regulations, *available at* http://www.painandthelaw.org/statutes/painpolicy_regulations.php.

Moreover, many but not all states have adopted prescription monitoring programs to deter illegal diversion. There is variation in the drugs covered and the type of monitoring utilized. *See, e.g.*, D. Joranson, *et al., Pain Management and Prescription Monitoring*, 23 J. Pain and Symptom Management 231, 233, Table 1, States with Prescription Monitoring Programs (2002) ("[i]n practice, [these programs] take different forms because each state government determines the goals, structure, and organization of its program.").

These differences in the regulation and prescribing of controlled substances would be inexplicable were the Attorney General, as he claims, in fact directed by the Controlled Substances Act to administer "uniform" regulation of controlled substances. See Pet. Brief at 14. The variation in state laws and physician practices that the Attorney General considers inappropriate is well-entrenched and will remain so regardless of the outcome of this case.

C. The Attorney General Could Apply His Interpretation to Interfere with Many Other Forms of End-of-Life Medical Care, Including Palliative Care and Refusals of Treatment

The analysis advanced by the Attorney General has implications far beyond the hastening of death under Oregon's Death With Dignity Act. Were the Attorney General's interpretation of his authority under the statutory scheme upheld, there would be nothing to prevent him from asserting federal control over all uses of controlled substances in medicine, including in connection with what are now common medical practices across the country. Although the Attorney General currently distinguishes practice under the Oregon statute from other medical uses of controlled substances, Interpretive Rule § 2, Pet. App. at 103a; Pet. Brief at 20 n.7, nothing in the legal analysis he advances provides a basis for drawing a clear line between practice under the Oregon statute and other uses of controlled substances in end-of-life medical care.

For example, many states now, by statute, permit doctors to prescribe sedation sufficient to ensure that a terminally ill patient does not feel pain or experience suffering, even if there is a risk that enough medication to quell the pain or suffering will also be lethal. *See, e.g.*, R.I. Gen. Laws Tit. 5, 5-37.4, *available at* http://www.rilin.state.ri.us/Statutes/TITLE5/5-37.4/INDEX.HTM. The expansive powers claimed by the Attorney General would permit him to conclude that such uses of controlled substances are outside of "the course of professional practice" or do not serve a "legitimate medical purpose," effectively nullifying all of these state laws by federal, executive fiat. The democratic choices of each state's voters could be overridden.

Controlled substances are also commonly prescribed to relieve pain in terminally ill patients who have chosen to refuse further life-sustaining care. If the Attorney General opposes such a patient's right to refuse care, as his filing in

the *Schiavo* case suggests, *Schiavo v. Schiavo*, No. 8:05-CV-530-T-27TBM, Statement of Interest of the United States, March 21, 2005 (M.D. Fla.), *available at* http://news.findlaw.com/hdocs/docs/schiavo/32105dojstmnt.pdf, he could effectively prevent the exercise of this right by threatening to revoke the license of any physician prescribing controlled substances to ease the pain of a patient who rejects further life-sustaining support. His view that the CSA authorizes him to create and implement uniform national rules reflecting what he considers to be "legitimate" medical uses of such substances would permit him to take this step even though the right of a competent, terminally ill patient to refuse such care is now well-established in the law and in medical ethics. Just as the Attorney General argues here that he is not interfering with the right of Oregon physicians to assist in hastening death, but is merely prohibiting the use of controlled substances for this purpose, he could similarly claim that he was not interfering in the right to refuse life-sustaining care, but only limiting the use of controlled substances in connection with it. The *Schiavo* case demonstrates that such concerns are not purely theoretical.

The federal act does not contemplate, much less authorize, administrative rulings by the Attorney General to curtail medical practices that do not conform to his views about how physicians should care for their patients. If the Court were to uphold the Attorney General's rule, however, this could occur. The CSA was not intended to subordinate medical practice to ideology.

D. The Interpretive Rule Also Intrudes on Other State Authority

The Attorney General's interpretive rule encroaches on traditional state authority in another respect: state law has traditionally governed the legality of a person's taking of his own life. Moreover, this issue is most appropriately governed

by legislation, not by executive or judicial order. As forcefully described by Justice Scalia in *Cruzan*:

> [T]he point at which life becomes "worthless," and the point at which the means necessary to preserve it become "extraordinary" or "inappropriate," are neither set forth in the Constitution nor known to the nine Justices of this Court any better than they are known to nine people picked at random from the Kansas City telephone directory; and hence, that even when it is demonstrated by clear and convincing evidence that a patient no longer wishes certain measures to be taken to preserve his or her life, it is up to the citizens of [the state] . . . to decide, through their elected representatives, whether that wish will be honored. It is quite impossible (because the Constitution says nothing about the matter) that those citizens will decide upon a line less lawful than the one we would choose; and it is unlikely (because we know no more about "life and death" than they do) that they will decide upon a line less reasonable.

497 U.S. at 293. Justice Scalia added that the view that government should not prohibit its citizens from ever choosing to end life is one "our States are free to adopt if they wish." *Id.* at 300.

The Attorney General's interpretive rule usurps this power from the states and from the voters of Oregon. It replaces their democratic choice about the range of options to be available for one of life's most intensely personal and important decisions with the preferences of a federal executive, unsupported by any formal administrative process.

Popular concern about end-of-life issues continues to grow. In the past three years, bills to legalize physician-assisted dying have been introduced in the legislatures of Arizona, California, Hawaii, Vermont, Wisconsin, and Wyoming. H.R. 2313, 47th Leg., 1st Reg. Sess. (Ariz. 2005), *available at* http://www.azleg.state.az.us/Format Document.asp?inDoc

=/legtext/47leg/1r/bills/hb2313p%2Ehtm&DocType=B;Assemb. 654, 2005-06 Reg. Sess. (Cal. 2005), *available at* http://info.sen.ca.gov/pub/bill/asm/ab_0651-0700/ab_654_bill_20050526_amended_asm.pdf; H.R. 1454, 23rd Legis. (Haw. 2005), *available at* http://www.capitol.hawaii.gov/session current/bills/ hb1454_.htm; H.R. 168, 68th Biennial Sess. (Vt. 2005), *available at* http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/bills/intro/H-168.HTM; Assemb. 348, 96th Leg. Sess., 2003-04 Reg. Sess. (Wis. 2003), *available at* http://www.legis.state.wi.us/2003/ data/AB-348.pdf; S. 7, 57th Leg., 2004 Budget Sess. (Wy. 2004), *available at http://legisweb.state.wy.us/2004 /introduced/SF007.pdf.* The Attorney General's interpretive rule would close the door to ongoing efforts in the "laboratory of the states" to address difficult issues at end of life through careful legal reform. *Glucksberg*, 521 U.S. at 737 (O'Connor, J. concurring).

The people of Oregon have made a reasonable policy choice that has worked as they intended. The Oregon statute authorizes medical care that is well within the legitimate practice of medicine as understood by many physicians, scholars of bioethics, and patients today. It does not conflict in any way with federal efforts to thwart drug trafficking, and is a legitimate exercise of state legislative power. This Court should not permit the Attorney General to block access by terminally ill Oregon patients to medications they request, that their physicians find appropriate, and that the people of Oregon have authorized them to obtain.

CONCLUSION

This Court should affirm the decision below.

Respectfully submitted.

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APPENDIX

APPENDIX

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AMICUS CURIAE

BRIEF

35

Supreme Court, U.S.
FILED
JUL 18 2005
OFFICE OF THE CLERK

No. 04-623

IN THE
Supreme Court of the United States

ALBERTO R. GONZALES, ET AL., PETITIONERS

v.

STATE OF OREGON, ET AL., RESPONDENTS.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* OF A COALITION OF MEDICAL ASSOCIATIONS AND SOCIETIES; PAIN, PALLIATIVE, AND ELDER CARE ASSOCIATIONS; AND DISTINGUISHED INDIVIDUAL PAIN, PALLIATIVE, AND ELDER CARE PROFESSIONALS IN SUPPORT OF RESPONDENTS

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TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES iii

INTERESTS OF *AMICI CURIAE* 1

SUMMARY OF THE ARGUMENT 7

ARGUMENT 7

I. THE TEXT OF THE CSA DOES NOT CONFLICT WITH THE ODWDA 8

II. WELL-ENTRENCHED PRINCIPLES OF FEDERALISM PRECLUDE INTERPRETING THE CSA TO PERMIT THE AG'S INTRUSION INTO AN AREA TRADITIONALLY RESERVED TO THE STATES 12

A. THE REGULATION OF MEDICINE IS A TRADITIONAL STATE FUNCTION 14

B. THE DIRECTIVE IMPEDES THE EXERCISE OF THIS TRADITIONAL STATE FUNCTION AND THWARTS THE ABILITY OF THE STATES TO ACT AS LABORATORIES OF DEMOCRACY 19

C. THE DIRECTIVE DIMINISHES DISCOURSE ON THE ETHICAL

AND PRACTICAL
IMPLICATIONS OF
PHYSICIAN-ASSISTED
SUICIDE 24

III. THE DIRECTIVE WILL INTERFERE WITH PAIN MANAGEMENT DECISIONS 25

CONCLUSION 30

TABLE OF AUTHORITIES

CASES

Buckman Co. v. Plaintiffs' Legal Comm.,
531 U.S. 341 16

Chevron U.S.A. Corp. v. Nat'l Res. Def. Council, Inc.,
467 U.S. 837 (1984) 12

Chisom v. Roemer,
501 U.S. 380 (1991) 1

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172 F.R.D. 681 (N.D. Cal. 1997) 18

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497 U.S. 261 (1991) 15, 19

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520 U.S. 806 (1997) 14, 16

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469 U.S. 528 (1985) 13

Gen. Dynamics Land Sys., Inc. v. Cline,
540 U.S. 581 (2004) 10

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125 S. Ct. 2195 (2005) 9

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501 U.S. 452 (1991) 12, 13

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268 U.S. 5 (1925) 15

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21 C.F.R. § 1306.04 11

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21 U.S.C. § 823(b)(2) 11

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INTERESTS OF *AMICI CURIAE*[1]

The American Academy of Pain Management ("AAPM"), California Medical Association ("CMA"), American Geriatrics Society ("AGS"), San Francisco Medical Society ("SFMS"), Society of General Internal Medicine ("SGIM"), Washington State Medical Association ("WSMA"), Medical Society of the State of New York ("MSSNY"), American Medical Student Association ("AMSA"), American Medical Women's Association ("AMWA"), National Academy of Elder Law Attorneys, Inc. ("NAELA"), Southern California Cancer Pain Initiative ("SCCPI"), Washington State End of Life Consensus Coalition ("WSEOLCC"), Washington Intractable Chronic Pain Association ("WICPA"), National Foundation for the Treatment of Pain ("NFTP"), American Pain Foundation ("APF"), Oregon Hospice Association, Inc. ("OHA"), American Academy of HIV Medicine ("AAHIVM"), American Academy of Hospice and Palliative Medicine ("AAHPM"), and a coalition of distinguished individual pain, palliative, and elder care professionals respectfully submit this brief as *amici curiae* in support of Respondents.

AAPM is the largest multi-disciplinary pain society in the United States. AAPM is a nonprofit credentialing society for pain management practitioners; its goals are bringing together the many clinicians who work with individuals in pain and assisting in the provision of quality services to those individuals.

CMA is a nonprofit, incorporated professional association of more than 30,000 physicians practicing in

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[1] Pursuant to Sup. Ct. R. 37.3(a), the parties have consented to the filing of this brief and copies of the consent letters are submitted herewith. Pursuant to Sup. Ct. R. 37.6, counsel for *amici* states that this brief was not authored, in whole or in part, by any counsel for a party, and no person, other than *amici*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief.

California. CMA's membership includes California physicians engaged in the private practice of medicine, in all specialties. CMA's primary purposes are "to promote the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession." CMA and its members share the objective of promoting high quality, cost-effective health care for Californians.[2]

AGS is a not-for-profit, organization of professionals who are specially trained in the management of care for frail, chronically ill, older patients. AGS is dedicated to improving the health, independence and quality of life of all older people. AGS promotes high quality, comprehensive and accessible care for America's older population, including those chronically ill and disabled.

SFMS is California's oldest medical association, having been first established just after the "gold rush" in the mid-1800s. A professional association for local physicians, SFMS is an advocate for physicians and their patients, providing education, advocacy, and referral information on a wide range of medical and public health topics. Well over 1,000 physicians of every medical specialty are members, and SFMS is represented on professional and government bodies throughout the city, state, and nation.

SGIM is a national association of over 3,000 physicians and other health professionals whose purpose is

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[2] As set forth in CMA's House of Delegates Resolutions 507a-95 and 516-97, CMA's current policy on physician assisted suicide is that, while physicians may diagnose a patient as having a terminal condition or illness and find a patient competent to make informed decisions, CMA continues to condemn voluntary active euthanasia by physicians as unethical and unacceptable. While opposition to the legalization of physician-assisted suicide remains the position of CMA, CMA remains receptive to multiple views and perspectives expressed by various participants in the public discourse on this issue and actively seeks input from all stakeholders in this important societal dialogue.

improving patient care, education and research in general internal medicine.

WSMA is a private, non-profit membership organization that represents over 9,000 physicians, residents, medical students, and physician-assistants throughout Washington. WSMA represents the professional interests of all member physicians, and promotes effective physician leadership in the evolving health care delivery system.

MSSNY, organized in 1807 and incorporated and operated under New York's Not-for-Profit Corporation Law, has approximately 27,000 physician, medical resident and medical student members, representing all medical specialties. The purposes of MSSNY include "[t]o enhance the delivery of medical care of high quality to all people in the most economical manner, and to act to promote and maintain high standards in medical education and in the practice of medicine in an effort to ensure that quality medical care is available to the public."[3]

AMSA is the nation's largest independent organization of physicians-in-training. Founded in 1950, AMSA is a non-profit organization that represents over two-thirds of all medical students and a total of 60,000 physicians-in-training. AMSA has chapters in every allopathic and osteopathic medical school in the country, and indeed represents the future of medicine in the United States.

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[3] MSSNY joins this brief despite its well-documented opposition to physician-assisted suicide—MSSNY joined *amicus* briefs in support of petitioners' eventually successful efforts to uphold state statutory bans on physician-assisted suicide in both *Vacco v. Quill*, 521 U.S. 793 (1997), and *Washington v. Glucksburg*, 521 U.S. 702 (1997). MSSNY shares the concern of the other *amici* here about (1) the Attorney General's unauthorized encroachment on the states' traditional regulation of medical practice and (2) the potential chilling effect of the Attorney General's Directive on physicians' willingness to administer proper palliative care.

AMSA's goal is to improve medical training and the nation's health.

AMWA is a non-profit association founded in 1915 to advance women in medicine and improve women's health. AMWA is the oldest and largest multispecialty organization of women physicians and health care professionals. AMWA empowers women to lead in improving health for all within a model that reflects the unique perspective of women.

NAELA is a non-profit association that assists lawyers, bar organizations, and others who work with older clients and their families. Established in 1987, NAELA provides information, education, networking and assistance to those who deal with the many specialized issues involved with providing legal services to the elderly and disabled. Its mission is to establish its members as the premier providers of legal advocacy, guidance, and services to enhance the lives of people as they age. Its members counsel older adults and families facing decisions on how to cope with serious chronic illness and ultimately decisions about end-of-life.

SCCPI, founded in 1993, is a nonprofit volunteer interdisciplinary organization made up of physicians, nurses, pharmacists, social workers and many other professionals dedicated to the relief of cancer pain. SCCPI works closely with other professional and regulatory agencies to remove barriers to optimum pain relief. SCCPI currently has approximately 2,200 individual members.

WSEOLCC's mission is to work collaboratively with organizations and individuals across Washington to develop and support innovative approaches for achieving excellence in care of the dying and to foster dialogue about death and dying within our communities. Since 1997, WSEOLCC, working together with the WSMA, has provided an ongoing venue for members from all communities in Washington to explore end of life issues together.

WICPA is a nonprofit educational and advocacy organization founded in 1991 that represents over 700 patients and physicians in the Pacific Northwest. WICPA assists intractable chronic pain sufferers to regain their self-respect, maintain their dignity, and receive treatment as necessary to allow each to function as normally as possible. Its purpose is to lessen the suffering of people with chronic pain by educating pain sufferers, physicians, and the public about intractable chronic pain and its management.

NFTP is a not-for-profit national organization that provides support for patients suffering from intractable pain, their families, friends, and their physicians through advocacy and education. NFTP's website, www.paincare.org, receives as many as 10,000 individual visits per day. NFTP also assists persons who cannot find physicians to treat their pain, supports those whose physicians refuse to treat them out of fear of sanctions and prosecution, and provides opportunities for people suffering from intractable pain to share their experiences with one another. These activities provide NFTP with a multidimensional understanding of how recent efforts by law enforcement to substitute its own judgment about the legitimate purposes medical decisions for those laid out professional guidelines, medical ethics and evidence-based clinical experience.

APF is the nation's largest nonprofit organization devoted exclusively to serving the needs of people with chronic and acute pain. Its mission is to improve the quality of life for all Americans with pain by raising public awareness, providing practical information, promoting research, and advocating removal of barriers to effective pain management. Its website, www.painfoundation.org, is a respected resource for patients and professionals alike. Through its outreach and patient support activities, APF is well-informed on the conditions under which those with chronic pain in must seek care.

OHA is a statewide, public benefit, nonprofit voluntary membership organization dedicated to ensuring and promoting high quality hospice and palliative care. OHA's first responsibility is to the public. In addition to public information, referral and advocacy, OHA provides education and technical assistance to more than 50 operating and developing hospice provider programs who are or will be serving dying Oregonians and their families and loved ones. OHA was authorized by Oregon to keep Oregon's Hospice Registry and is recognized as an accrediting body for hospices in legislation passed in 1987. In 1992, OHA was assigned authority by the legislature to ensure compliance with Or. Rev. Stat. §§ 443.850-870, Oregon's regulatory scheme for hospice programs.

AAHIVM is an independent organization of HIV specialists and others dedicated to promoting excellence for all patients in HIV/AIDS care. As the largest independent organization of HIV frontline providers, AAHIVM's 2,000 members provide direct care to more than 340,000 HIV patients—more than two thirds of the patients in active treatment for HIV disease.

AAHPM is an organization of physicians and other medical professionals dedicated to excellence in and the advancement of palliative medicine through prevention and relief of patient and family suffering by providing education and clinical practice standards, fostering research, facilitating personal and professional development, and by public policy advocacy.

The individual *amici* are licensed medical professionals and educators with substantial expertise in confronting pain management and end-of-life issues faced by terminally ill patients.[4]

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[4] *See* Addendum A for a fuller description of each of the individual *amici*.

SUMMARY OF THE ARGUMENT

We respectfully urge the Court to affirm the decision of the Court of Appeals permanently enjoining enforcement of the Directive issued by the Attorney General ("AG") interpreting the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-904, to preclude physicians from taking actions consistent with the Oregon Death With Dignity Act ("ODWDA"), Or. Rev. Stat. §§127.800-127.897.

The Directive, an agency statement issued with no public comment, directs the Drug Enforcement Administration ("DEA") to investigate and prosecute physicians who prescribe medications to terminally ill patients that hastens their deaths consistent with the detailed requirements of democratically-enacted state legislation. The AG's unprecedented and unilateral determination upsets a longstanding tradition of deference to state regulation of medical practice while interfering with both the ODWDA and physicians' ability to care for terminally ill patients nationwide. The Directive will also cut off a robust political debate explicitly sanctioned by this Court. Finally, the Government's amorphous justification for the Directive will, by its very breadth and vagueness, cast a pall over physicians' decisionmaking. Confronted with the formidable possibility of medically untrained enforcement officers shadowing their decisionmaking, physicians will retreat from their obligations to their terminally ill patients.

ARGUMENT

With the ODWDA, Oregon voters enacted a law that allows, in some circumstances and under careful criteria, a physician to prescribe medication that has the effect of hastening the death of terminally ill patients. The AG does not agree and has sought to overturn this statute by creating, in the Directive, a result-oriented and indefensible interpretation of a decades-old federal statute, the CSA, with the result being that the AG now claims the authority to

determine the confines of legitimate medical practice. Until the Directive, it had never been seriously contemplated that the CSA permits the federal government to unilaterally replace the states as regulators of the medical profession. Yet, the AG has relegated to himself the exclusive right both to define what a legitimate medical practice is and to prosecute purported violators. He simply cannot do this.

First, the text of the CSA does not in any way delegate such extraordinary power to the AG. The CSA delegates to the AG the authority to combat drug abuse and the illicit traffic of controlled substances—not the authority to regulate the practice of medicine generally. Indeed, far from being at odds with the ODWDA, the CSA contemplates that, under proper medical supervision and under *state* regulation, doctors *can* prescribe controlled substances to alleviate pain. Second, the Directive alters the federal-state balance without a grant of authority by Congress, thus destroying this Court's promise of a state-level resolution to this important public policy issue. The serious constitutional problems raised by the AG's argument give added force to an interpretation of the CSA that allows states to continue their historical role as regulators of the medical profession. Third, the Directive would unavoidably have a profoundly chilling effect on physicians' medical judgment. Faced with prosecution, physicians will err on the side of caution and undertreat chronic and irreversible pain sufferers.

Moreover, the Directive will stall the development of medical knowledge in the end-of-life and palliative care fields. While the merits of physician-assisted suicide can, and should, be debated, the states should be permitted to determine policy for their own medical communities.

I. THE TEXT OF THE CSA DOES NOT CONFLICT WITH THE ODWDA

The AG's primary argument is that the federal scheme established by the CSA for the regulation of the

distribution of controlled substances includes the power to define the "legitimate medical purpose[s]" for which controlled substances can be prescribed. *See* Br. for Pet'rs at 14-18. To the contrary, the text of the CSA, settled canons of statutory construction, and over 100 years of deference to state regulation of medical practices have placed the regulation of legitimate medical practice with the states. The text of the CSA "provide[s] no indication—much less an 'unmistakably clear' indication—that it intended to authorize the Attorney General to regulate the practice of physician assisted suicide." *Oregon v. Ashcroft*, 368 F.3d 1118, 1125 (9th Cir. 2004). Rather, the CSA delegates to the AG only the authority to regulate controlled substances as necessary to combat drug abuse and drug trafficking.

As this Court recently noted, the CSA was "the first campaign" of a "national 'war on drugs.'" *Gonzalez v. Raich*, 125 S. Ct. 2195, 2201 (2005). "Congress set out to enact legislation that would . . . provide meaningful regulation over legitimate sources of drugs to prevent diversion into illegal channels, and strengthen law enforcement tools against the traffic in illicit drugs." *Id.* It thus cannot be doubted that "[t]he main objectives of the CSA were to conquer drug abuse and to control legitimate and illegitimate traffic in controlled substances," *id.* at 2203, and not the wholesale regulation of medical practice.

Indeed, the text of CSA itself clearly evidences its purpose to be the prevention of drug abuse and trafficking, rather than general regulation of medical practice. The Congressional findings within the CSA that recite that "[a] major portion of the *traffic* in controlled substances flows through interstate and foreign commerce," and that "[f]ederal control of the intrastate incidents of *traffic* in controlled substances is essential to the effective control of the interstate incidents of such *traffic*." 21 U.S.C. §§ 801(3) & (6) (emphases added). This purpose is even exhibited by the titles of the acts and amendments passed by Congress. For

example, the 1970 act of which the CSA was one part, Pub. L. 91-513, was named the Comprehensive Drug Abuse Prevention and Control Act of 1970. Similarly, the 1974 amendments were enacted through the Narcotic Addict Treatment Act of 1974, Pub. L. 93-281; the 1986 amendments included the Juvenile Drug Trafficking Act of 1986, Pub. L. 99-570, and the Anti-Drug Abuse Act of 1986, Pub. L. 99-570.[5]

To combat the illicit drug trade, the CSA authorizes the AG to place a drug on one of five schedules of controlled substances and to regulate their distribution. *See* 21 U.S.C. § 811. In deciding whether or not to schedule a drug at all, the AG must evaluate eight Congressionally-defined factors. *See* 21 U.S.C. § 811(c). *Each* of these factors speaks to the potential for a drug to be abused and/or to lead to dependence. *Id.* *None* of these factors depends on the potential medical uses, legitimate or otherwise, of a drug. *Id.*

After a determination to schedule a drug under § 811, Congress, in § 812, required three findings to determine the proper schedule. The first finding relates to the "potential for abuse." *See, e.g.*, § 812(b)(1)(A). The third finding similarly relates to the potential for "psychological or physical dependence." *See, e.g.*, § 812(b)(1)(C). The second finding, whether or not the drug has a "currently accepted medical use," *see, e.g.*, § 812 (b)(1)(B), must be read in light of the context of these other two required findings. *See Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 596 (2004) (noting "the cardinal rule that a statutory phrase must be read in context since a phrase gathers meaning from the words around it" (internal quotations and alterations omitted)). In an act directed at limiting drug trafficking and abuse, and sandwiched between two provisions directing the AG to

[5] *See also, e.g.*, Drug Addiction Treatment Act of 2000, Pub. L. 106-310; Controlled Substances Trafficking Prohibition Act , Pub. L. 105-277; Anti-Drug Abuse Amendments of 1988, Pub. L. 100-690.

determine the potential for abuse and addictive properties of a drug, the AG's authority to determine whether a drug has an "accepted medical use," logically must be interpreted to authorize a determination of whether there is any accepted medical use other than the facilitation of drug abuse. Congress, when instructing the AG to determine whether a controlled substance has an "accepted medical use" thus did not intend to give the AG the ability to determine the propriety of the various medical uses of medications.

Nor does 21 C.F.R. § 1306.04, which directs the AG to prohibit a practitioner from prescribing controlled substances except for a "legitimate medical purpose," give the AG the authority for the wholesale regulation of the practice of medicine. This phrase, read in the context of the CSA, differentiates between prescriptions made with the legitimate medical interests of patients in mind and those made to further drug abuse, addiction, and trafficking.

Every case the AG cites for the proposition that courts have "recognized and enforced the CSA's prohibition on the prescription of controlled substances for other than legitimate medical purposes" involves cases where physicians prescribed medications in a manner that could aide drug abusers. *See* Br. of Pet'rs at 16-17. Conversely, where a prescription is written for a *bona fide* medical purpose, the AG cannot unilaterally determine that medical purpose to be illegitimate. Instead, the AG must defer to the states and state standards of medical care—areas firmly within the states' traditional regulation of the practice of medicine. *See infra* Part II. Indeed, Congress included in the CSA specific references to state regulation. For example, § 823(a)(2) & (b)(2) instruct the AG to consider "compliance with applicable State and local law" when registering manufacturers and distributors. Similarly, § 824(a)(3) instructs the AG to consider whether a physician is "authorized by State law to engage in the manufacturing,

distribution, or dispensing of controlled substances" when making a physician registration determination.

Even if the CSA were ambiguous—and it is not—"to give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which [this Court] relied to protect states' interests." *Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991) (internal quotation omitted) (alteration in original).[6] "Traditional tools of statutory construction" preclude the AG's interpretation because the CSA shows no intent to take away the states' power to regulate medicine. *See Chevron U.S.A., Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837, 843 n.9 (1984) ("If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect."). Specifically, when viewed in light of the traditional reservation of the regulation of medicine to the states, the presumption against alterations in the federal-state balance and the canon of constitutional avoidance compel the conclusion that the AG has no authority to define "legitimate medical practice."

II. WELL-ENTRENCHED PRINCIPLES OF FEDERALISM PRECLUDE INTERPRETING THE CSA TO PERMIT THE AG'S INTRUSION INTO AN AREA TRADITIONALLY RESERVED TO THE STATES

Any potential interpretation of a federal statute that intrudes into an area traditionally reserved to the states must be scrutinized in the context of our uniquely compound system of government. Through the division of political

[6] Recently, Congress has twice rejected federal proscription of physician-assisted suicide by failing to enact bills substantially similar to the Directive. *See* Joseph Cordaro, Note, *Who Defers to Whom?*, 70 Fordham L. Rev. 2477, 2485-86 (2002) (recounting the defeats of the Lethal Drug Abuse Prevention Act and the Pain Relief Promotion Act).

power between the states and the federal government, federalism helps secure several important values: "It assures a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive by putting the States in competition for a mobile citizenry." *Gregory v. Ashcroft*, 501 U.S. at 458 (citations omitted). "The essence of our federal system," according to Justice Blackmun, "is that . . . the States must be equally free to engage in any activity that their citizens choose for the common weal, no matter how unorthodox or unnecessary anyone else . . . deems state involvement to be." *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 546 (1985).

To ensure respect for this federalist structure, even where Congress' power to legislate is undisputed, this Court has insisted that before a law invades the states' traditional province, Congress must clearly express its intent to do so. *See Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 365-66 (2002); *Solid Waste Agency v. United States Army Corps of Eng'rs*, 531 U.S. 159, 172-73 (2001); *Gregory v. Ashcroft*, 501 U.S. at 460 (infringing on "state governmental functions" is "a power that we must assume Congress does not exercise lightly").

In a recent case strikingly similar to this one, where a federal agency sought to extend the reach of a statute into an area traditionally reserved to the states, this Court reaffirmed these principles. In *Solid Waste Agency*, the Army Corps of Engineers ("Corps") sought to expand federal power to regulate "navigable waters" under the Clean Water Act ("CWA") to include intrastate waters used as habitat by migratory birds. The Court refused to allow this interpretation of "navigable waters", reasoning in part that such an interpretation was disfavored in that it would encroach into an area traditionally reserved to the states:

> Where an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result. This requirement stems from . . . our assumption that Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority. This concern is heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power. Thus, where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress.

Solid Waste Agency, 531 U.S. at 172-73 (citations and internal quotation omitted). Here, not only is there no clear Congressional intent to give the AG the power he claims, but it is also settled law that the regulation of medical practice is a traditional state power.

A. THE REGULATION OF MEDICINE IS A TRADITIONAL STATE FUNCTION

This Court has long recognized that the regulation of legitimate medical practice is within the states' province. *See Pegram v. Herdrich*, 530 U.S. 211, 237 (2000) ("[H]ealth care" is a "subject of traditional state regulation"); *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997) ("[T]he historic police powers of the State include the regulation of matters of health and safety."); *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977) ("It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the

health professions."). As early as 1925, this Court overturned a federal conviction that purported to discern the intent of a physician in prescribing medicine. In that case, *Linder v. United States*, 268 U.S. 5 (1925), the Government prosecuted a doctor for dispensing illegal drugs to an addict under the Harrison Act, the CSA's predecessor statute; this Court reversed the doctor's conviction. In doing so, this Court noted that "direct control of medical practice in the states is beyond the power of the Federal Government." *Id.* at 18. The CSA has not changed this balance. Thus, in 2002, this Court called "the field of health care" "a subject of traditional state regulation," in discussing "quintessentially state-law standards of reasonable medical care." *Rush Prudential*, 536 U.S. at 387 (quotations omitted).

This Court has likewise affirmed the states to be the primary regulators of medicine in the context of the treatment of the incapacitated and terminally ill. In *Cruzan v. Missouri*, 497 U.S. 261 (1991), this Court addressed a constitutional challenge to a state's refusal of a family's request to take a patient off life-support. The State argued that the regulation of medicine was an area reserved to the states. This Court agreed, affirming states' rights to define legitimate medical practice. More recently, in *Washington v. Glucksberg*, 521 U.S. 702 (1997), this Court declared that, within constitutional limits, the states are the appropriate forum for decisions about assisted suicide. *See id.* at 728-36. Together, these decisions evidence a strong preference for continuing the tradition of state regulation of medicine.

Only when Congress declares a clear intent to intrude into the states' regulation of medicine will this preference be disturbed. The AG can point to no such intent. The CSA was enacted to confront the illegal drug trade, not to nationalize the regulation of medicine. *See supra* Part I. The House Report states that the CSA was "designed to deal . . . with the growing menace of drug abuse." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567.

That "menace" consisted of the deleterious effects of drugs like cocaine and consequential crime. *Id.* at 4572-75. The CSA therefore created a "closed system" to "reduce the widespread diversion of these drugs out of legitimate channels into the illicit market." *Id.* at 4572. In other words, the CSA prevents drug *abuse* by regulating drug distribution; it does not regulate drug *use* within legitimate channels. Congress thus drew a careful line between regulating the drug trade and regulating the medical profession. To interpret the CSA to permit the regulation of pain care would erase this line and turn the statute on its head.[7]

As the AG points out, the CSA does provide for broader regulation in one medical area—"maintenance" and "detoxification" treatment of addicts. *See* Br. for Pet'rs 33-34 (§§ 802(28) & (29)). However, the treatment of drug abusers is directly related to the CSA's express purpose and Congress gave explicit authority for the regulation of these programs in the text.[8] Even in these provisions, Congress empowered the Secretary of Health and Human Services ("HHS") to regulate—not the AG. *See* 21 U.S.C. § 823(g).

There is thus *nothing* in the statute or its legislative history to suggest that Congress wanted the AG to second-guess the states' delineation of legitimate medical practice.[9]

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[7] Congress drew, and this Court has given effect, to a similar delineation between federal regulation of employee health benefit plans under ERISA and state control over the healthcare professions. *See Pegram*, 530 U.S. at 236; *De Buono*, 520 U.S. at 814.

[8] *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513 (2002) ("exclussio unius est exclusio alterius").

[9] Even the FDCA, 21 U.S.C. § 301, *et seq.*, while authorizing the FDA to approve drugs for a specific medical purpose, does not empower the FDA to prevent physicians from prescribing those medications for unapproved, or "off-label," medical uses. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001) ("'[O]ff-label' usage . . . is an accepted and necessary corollary of the FDA's mission to

If Congress had intended such sweeping changes in the balance of state and federal power, it would certainly make such intent clear.[10] The authority to prosecute doctors for violating a professional standard is hardly the same thing as defining what the standard is. It is analogous to a highway patrolman conferring to him or herself the power not only to enforce the speed limit but also to decide what the speed limit should be. One therefore cannot convert the DEA's power to *apply* a rule into the power to *create* a rule.

The AG also relies on the 1984 amendments that enlarged the grounds for revocation of a physician's registration. *See* Br. for Pet'rs at 34-35. Section 824(a)(4), as amended, permits the AG to terminate a registration if that registration is "inconsistent with the public interest." Section 823 provides five factors that the AG must consider. Two of the factors involve the registrant's compliance with state or federal law. A third is a catch-all provision. The other factor relevant here instructs the AG to look to the acts of the physician's *state* licensing authority.[11] Of course, state licensing authorities define their own standards of legitimate medical practice. None of these factors suggest that Congress sought to regulate medicine or to permit the AG to define legitimate medical practice nationally. Indeed, in 1998—more than a decade after the amendments—the Justice Department issued an opinion stating that "[t]here is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a State's determination as to what constitutes

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regulate in this area without directly interfering with the practice of medicine.").

[10] *See Chisom v. Roemer*, 501 U.S. 380, 396 n.23 (1991) ("Congress' silence in this regard can be likened to the dog that did not bark. *See* A. Doyle, *Silver Blaze*, *in* The Complete Sherlock Holmes 335 (1927).")

[11] 21 U.S.C. §§ 823(f).

legitimate medical practice in the absence of a federal law prohibiting that practice."[12]

In its about-face that came with the change of administration, the AG now claims that the 1984 amendments' "public interest" criterion permits it to define legitimate medical practice. But the AG could always revoke registrations once certain prerequisites were met. Expanding the statute's reach over physicians' registrations cannot plausibly be equated with granting the Federal government additional powers to define what is legitimate medical treatment. In fact, as the one case interpreting the public interest criterion has held, the amendments did not expand the areas in which the AG could regulate.

In that case, *Conant v. McCaffrey*, 172 F.R.D. 681 (N.D. Cal. 1997), plaintiffs sought a preliminary injunction precluding the AG from taking action against physicians for discussing medical uses of marijuana. The AG argued that the CSA gave the DEA "broad authority" to "revoke a physician's license for any act that violates the public interest." *Id.* at 699. The court squarely rejected this contention, finding that the "public interest" criterion did not permit the AG to create standards for appropriate medical treatment. To the contrary, the court concluded, "only convictions or uncharged criminal activity in violation of federal, state, or local law would suffice to establish a violation of the public interest." *Id.* at 700.

As *Conant* demonstrates, there is no basis for inferring that the "public interest" criterion allows the AG to determine the legitimacy of a medical practice: By finding that the public interest criterion is limited to violations of existing law, the *Conant* court correctly determined that the amendments left the historic federal-state balance intact.

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[12] Letter for the Hon. Henry Hyde from the Hon. Janet Reno, Attorney General of the United States (June 5, 1998).

B. THE DIRECTIVE IMPEDES THE EXERCISE OF THIS TRADITIONAL STATE FUNCTION AND THWARTS THE ABILITY OF THE STATES TO ACT AS LABORATORIES OF DEMOCRACY

The Directive not only conflicts with the legislation it seeks to execute, but also impedes the states' ability to act as laboratories for the development of public policy. Justice Brandeis expressed this system's genius: "It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). Echoing this view, Justice Kennedy observed that "the States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear." *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring).

This Court has encouraged state experimentation in the area of care for the terminally ill or incapacitated. In *Cruzan*, Justice O'Connor emphasized that such deference is the *best* way for society to balance the various interests in end-of-life decisionmaking: "Today we decide only that one State's practice does not violate the Constitution; the more challenging task of crafting appropriate procedures for safeguarding incompetents' liberty interests is entrusted to the 'laboratory' of the States." 497 U.S. at 292 (O'Connor, J., concurring) (citation omitted).

More recently, in cases addressing the constitutionality of assisted suicide, this Court noted that "Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue,

as it should in a democratic society." *Glucksburg*, 521 U.S. at 735. The majority noted with approval the deliberation of many states on the subject: "States are currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues." *Id.* at 716-19. Justice O'Connor likewise elaborated: "As the Court recognizes, states are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues. *In such circumstances, the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the laboratory of the States.*" *Id.* at 737 (O'Connor, J., concurring) (citations and internal quotation omitted) (emphasis added); *see also id.* at 786-89 (Souter, J., concurring).

In line with this Court's suggestions, Oregonians have repeatedly examined the issues surrounding assisted death. The state's citizens enacted the ODWDA in 1994 by majority vote. During a court challenge to the ODWDA, the legislature put the issue back before the voters. Oregonians reaffirmed their decision by a 60% to 40% vote. *The question is not whether one agrees with the substance of Oregon's decision*; the question is whether Oregon has acted in the fashion this Court mandated. It unquestionably did.

Significantly, the Directive endangers not only Oregon's legislative process, but also the many varied efforts undertaken by state legislatures around the country. A number of states—New York,[13] Maine,[14] Hawaii,[15] and Rhode Island[16]—are currently considering or recently considered statutes similar to the ODWDA. Just this year, the California Legislature referred a bill, modeled on the ODWDA, to the House Committee on Appropriations where it passed 11 to 6 after amendment,[17] while the Vermont Legislature heard testimony on a bill that would mirror the ODWDA.[18]

Conversely, many states, including North Carolina,[19] Massachusetts,[20] and Alabama,[21] have enacted or are considering bills that would criminalize physician-assisted suicide. Some states, like Ohio, have made it subject to medical board disciplinary action,[22] while others, like Kansas, have created a civil cause of action against physicians who assist a suicide.[23] New Hampshire[24] and Wisconsin[25] both considered laws allowing physicians to

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[13] *See* S. 677, 224th Ann. Legis. Sess. (N.Y. 2002).

[14] *See* Maine Death with Dignity Act, *available at* http://www.maine.gov/sos/cec/elec/2000g/refguide.htm (last visited July 6, 2005) (the referendum failed 49% to 51%).

[15] *See* S. 2745, 22nd Leg., Reg. Sess. (Haw. 2002); H.R. 2487, 21st Leg., Reg. Sess. (Haw. 2002). H.R. 2487 passed the House, but did not pass in the Senate. S. 2745 failed to pass the Senate by a margin of 11 to 14. In January 2005, the Senate introduced another bill modeled on the ODWDA to the Committee on Health. *See* S. 1307, 23d Leg., Reg. Sess. (Haw. 2005). Hawaii also considered a ballot initiative to amend its constitution. *See* S. 2749, 21st Leg., Reg. Sess. (Haw. 2002).

[16] *See* S. 2763, Gen. Ass., Jan. Sess. (R.I. 2002).

[17] *See* Assemb. B. 654 2005 Sess. (Cal. 2005). The bill also passed the Committee on Judiciary with amendment 5 to 4.

[18] *See* H. 168, 2005-06 Leg. Sess. (Vt. 2005).

[19] *See, e.g.*, S. 389 & 390, 2001 Gen. Assem. (N.C. 2001).

[20] *See* H.R. 4550, 182d Gen. Court, 2001-02 Sess. (Mass. 2001). The House Committee determined H.R. 4550 eligible for Executive Session.

[21] *See* H.R. 739 2004 Reg. Sess. (Ala. 2004).

[22] *See* Ohio Rev. Code Ann. 4731.22 and 3795.01 (West 2005).

[23] *See, e.g.*, Kan. Stat. Ann. § 60-4405 (2003).

[24] *See* H.R. 1209, 157th Gen. Court, 2001 Sess. (N.H. 2001). The bill did not pass the house.

[25] Assemb. B. 417, 95th Leg., 2001 Reg. Sess. (Wis. 2002); Assemb. B. 184, 95th Leg., 2001 Reg. Sess. (Wis. 2002). Both bills failed to pass pursuant to a Senate Joint Resolution. Notably, Wisconsin considered similar legislation in tandem with a bills legalizing such treatment (which

refuse physician-assisted suicide on moral grounds without adverse employment repercussions. Finally, states are increasing education on end-of-life care issues.[26]

Here, Oregon's role becomes especially important; it is the only jurisdiction that can provide any statistical evidence.[27] Regardless of one's position, the ODWDA has provided and continues to provide useful empirical evidence.[28] This would be lost, though, if executive fiat replaces legislative (and popular) deliberation. In *Glucksberg*, Justice Souter noted that the states "have superior opportunities to obtain the facts necessary for a judgment about the [instant] controversy." *Glucksberg*, 521 U.S. at 788 (Souter, J., concurring). The paucity of data prompted the Justices to suggest that the states perform their traditional roles as experimenters. Justice Souter noted: "The day may come when we can say with some assurance which side is right, but for now it is the substantiality of the factual disagreement, and the alternatives for resolving it, that matter." *Id.* at 786. Here, the states must be permitted to play "their role as laboratories for experimentation . . . where the best solution is far from clear." *Lopez*, 514 U.S. at 581 (Kennedy, J., concurring); *see also Vacco v. Quill*, 521 U.S. 793, 806-808 (1997) (recounting the development New York's laws concerning assisted-suicide and refusal of treatment).

These debates embody Justice Brandeis' observation about federalism's utility; each state is developing a largely unique response to a public policy issue of great importance. There is no consensus yet, either among state legislatures or within the medical field. As the District Court noted, "[w]ithout doubt there is a tremendous disagreement among highly respected medical practitioners as to whether assisted suicide or hastened death is a legitimate medical practice."[29]

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also failed to pass pursuant to a Senate Joint Resolution). *See* S. 184, 2001-02 Leg., Reg. Sess. (Wis. 2001).

[26] *See, e.g.*, Act of June 4, 2001, ch. 358, part LL, 2001 Me. Legis. Serv. 358 (West); Act of Oct. 5, 2001, ch. 518, 2001 Cal. Leg. Serv. 518 (West); Education on Physician-Assisted Suicide, S. 390, 2001 Gen. Assem., Reg. Sess. (N.C. 2001); S. 636, 2002 Leg., Reg. Sess. (Fla. 2002).

[27] For example, Oregon's experience has *not* borne out predictions by detractors that the ODWDA would have a negative effect on pain management. *See, e.g.*, Linda Ganzini et al., *Oregon Physicians' Attitudes About and Experiences With End-of-Life Care*, 285 J. Am. Med. Ass'n 2363, 2365 (2001). Nor after nearly seven years has the ODWDA lead to the abuse predicted by some. *See* William McCall, *Assisted Suicide Cases Down in '04*, The Columbian, Mar. 11, 2005, at C2 ("There is no evidence of abuse or coercion or misuse of the [ODWDA] policy."); *see also* Katrina Hedberg et al., Letter to the Editor, *Legalized Physician-Assisted Suicide in Oregon, 2001*, 346 N. Engl. J. Med., Vol. 450, 450-52 (2002); Robert Steinbrook, Health Policy Reports, *Physician-Assisted Suicide in Oregon*, 346 N. Engl. J. Med. 460, 462 (2002) ("Despite predictions of wide use, only a small number of patients in Oregon have received prescriptions for lethal doses of medication . . . ."); *id.* ("According to the Oregon Health Division, there is no evidence that the law has been abused.").

[28] *See, e.g.*, Ganzini, *supra*, at 2369 ("Studies from Oregon offer a rare opportunity to examine changes in end-of-life care in the context of legalized assisted suicide.").

[29] Surveys show that the medical community is neither universally for nor universally against the practice. In a recent nationwide survey of physicians, "45% believed that physician-assisted suicide should definitely or probably be legal, 34% believed that it should definitely or probably be illegal, and 22% were uncertain." Simon N. Whitney et al., *Views of United States Physicians and Members of the American Medical Association House of Delegates on Physician-assisted Suicide*, 16 J. Gen. Internal Med. 290, 292-93 (2001). Other surveys have reported conflicting results. *See, e.g.*, Jerald G. Bachman et al., *Attitudes of Michigan Physicians and the Public Toward Legalizing Physician-assisted Suicide and Voluntary Euthanasia*, 334 N. Engl. J. Med., Vol. 303 (1996); Ezekiel Emanuel et al., *Euthanasia and Physician-assisted Suicide*, 347 Lancet 1805 (1996); Melinda A. Lee *et al.*, *Legalizing Assisted Suicide*, 334 N. Engl. J. Med. 310 (1996). Recent survey data indicates that the public supports pain alleviation treatment that hastens death. *See, e.g.*, Kenneth Jost, *The Right to Die*, 15 CQ Researcher 423, 428-29 (2005) (reporting a May 2003 Gallup survey finding that 72% of

Oregon v. Ashcroft, 192 F. Supp. 2d 1077, 1092 (D. Ore. 2002). Yet, this state-level discussion is precisely what this Court recognized as the appropriate forum for exploring such issues. The Directive threatens to foreclose further democratic deliberation through executive edict.

C. THE DIRECTIVE DIMINISHES DISCOURSE ON THE ETHICAL AND PRACTICAL IMPLICATIONS OF PHYSICIAN-ASSISTED SUICIDE

A clear benefit of the state-level debate is that medical professionals—those with the most experience, knowledge, and understanding of these difficult issues—have been able to speak their minds, deliberate upon the difficult issues at stake, propose public policy, and work with states on legislation. For example, the Center for Bioethics at the University of Pennsylvania Health System convened a national panel of experts on assisted-suicide. "The panel's goal was not to argue pros and cons, but to find common ground in examining how to guide practices and determine safeguards that would keep assisted suicide voluntary, regulated, and an option of last resort."[30] As Project Director Lois Snyder explained, the impetus behind the project was that "[t]he public, physicians, and policymakers clearly want—and need—thoughtful direction."[31] Recently the Center's Director, Arthur Caplan, commented on the ODWDA, stating that the "data confirms, for the seventh year, that the policy in Oregon is working. There is no evidence of abuse or coercion or misuse of the policy." William McCall, *supra*, at C2.

Americans agree that doctors should be allowed to end a terminal patient's life "by some painless means if the patient requests it.").

[30] Center for Bioethics, *Penn Bioethicists Lead National Panel on Assisted Suicide*, Mar. 20, 2000, *available at* http://www.bioethics.upenn.edu/press/?pageId=13 (last visited July 6, 2005).

[31] *Id.*

Another notable contribution is the Consensus Panel on End-of-Life Care begun in 1997 by the American College of Physicians—American Society of Internal Medicine.[32] The Panel's goal has been "to develop papers on the care of the dying under the College's Center for Ethics and Professionalism. The papers are used as training guides in conferences, hospital seminars, medical training programs and professional meetings."[33]

Implementation of the Directive will cause doctors to refuse to speak for fear of unwanted scrutiny from law enforcement, thereby freezing the democratic process essential to arriving at legitimate public policy.

III. THE DIRECTIVE WILL INTERFERE WITH PAIN MANAGEMENT DECISIONS

As demonstrated above, the Directive adversely impacts policy development in this difficult area. Equally important is its effect on the practice of medicine. The intrusion of an ill-equipped DEA into the oversight of physicians' decision-making creates fear among physicians who treat terminally ill patients. Moreover, the potential scope of the Directive, if upheld, makes it difficult for physicians to determine what conduct runs afoul of the law. Several features of the Directive are especially alarming.

First, by claiming the power to define "legitimate medical purpose," the AG seeks to vastly expand his jurisdiction over medicine. Indeed, the very notion that the AG is now empowered to determine the legitimacy of a particular medical practice is itself sufficient to cause

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[32] *See* ACP-ASIM, *ACP-ASIM Opposes Physician Assisted Suicide*, Nov. 1, 2000, *available at* http://www.acponline.org/college/pressroom/pas110100.htm (last visited July 6, 2005).

[33] *Id.*

alarm.[34] Until now, the DEA has not asserted that it alone can determine that otherwise appropriate state-sanctioned treatment is criminal.[35] The Directive gives doctors a short menu of unpalatable choices: undermedicate to avoid second-guessing by the DEA (harming patients); medicate pursuant to full disclosure (risking prosecution); or medicate and lie (again risking prosecution). Nothing in the CSA demands this choice; only the Directive forces physicians to choose between their patients and their freedom.

The threat of prosecution is not a trivial concern; investigations alone can result in the loss of reputation and privileges similar to the loss of a license.[36] Some physicians already practice "defensive medicine" in this area because of anxieties about legal repercussions.[37] Even a few prosecutions would lead physicians to "act on the perception that they are going to get into trouble. And as a result the

[34] Bringing the DEA into this context is a marked departure from past practice. A 1998 study of prosecutions of medical personnel for their pain management of dying patients found that *none* of the investigations were initiated by the state, but were instead the result of "informants" bringing cases to the authorities' attention. *See* Ann Alpers, *Criminal Act or Palliative Care?*, 26 J. L. Med. & Ethics 308, 315 (1998).

[35] *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), is not to the contrary. The Court held that the CSA should not be read with an implicit medical necessity defense for the distribution of a Schedule I drug. The case is inapposite for a variety of re sons, including that a distributor rather than a physician or patient sought to use the defense and that the drug at issue was a Schedule I drug, which by definition has *no* currently accepted medical use. *See id.* at 499-501. (Stevens, J., concurring).

[36] *See* Ann M. Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain*, 26 J. L. Med. & Ethics 332, 340 (1997).

[37] *See* Marshall B. Kapp, *Treating Medical Charts Near the End of Life*, 28 U. Tol. L. Rev. 521, 523 (1997).

patient is undertreated."[38] Research suggests that physician attitudes remain strongly biased toward risk reduction and away from pain alleviation:[39]

> [H]owever weak the factual foundations, the anxieties felt by physicians and other health care providers about potential criminal, civil, and/or regulatory liabilities are real and palpable influences on the quality and humanity of medical care actually provided to the most vulnerable patients. This is true even for those physicians who understand that their own legal exposure is minimal.[40]

In fact, a 1991 HHS report found that "[p]hysicians' fear of investigation remains a leading cause of pain undertreatment."[41] The Directive exacerbates such concerns.

In upholding the right of physicians to advise their patients on the medicinal use of marijuana, the Ninth Circuit similarly recognized the essential dilemma posed by federal intrusion into the regulation of medical treatment. *See Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002). Judge Kozinski emphasized that, while doctors "derive no direct

[38] *See* Rima J. Oken, Note, *Curing Healthcare Providers' Failure to Administer Opioids in the Treatment of Severe Pain*, 23 Cardozo L. Rev. 1917, 1944 (2002).

[39] *See* Martino, *supra*, at 332; *see also* Alpers, *supra*, at 308; J. David Haddox & Gerald M. Aronoff, Commentary, *The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain*, 26 J. L. Med. & Ethics 350, 351 (1998); Sandra H. Johnson, *Disciplinary Actions and Pain Relief*, 24 J. Law, Med. & Ethics 319-27 (1996); Michael J. Reynolds, Note, *Morphine or Malpractice*, 15 St. John's J. Legal Comment. 79, 83 (2000) (citing C. Stratton Hill, Jr., *Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin*, 11 J. Pain & Symptom Mgmt. 287, 289-92 (1996)).

[40] Kapp, *supra*, at 545.

[41] Oken, *supra*, at 1944.

benefit" from recommending marijuana use to patients "other than the satisfaction of doing their jobs well[,] . . . the *burden* of the federal policy the district court enjoined falls directly and personally on the doctors." *Id.* at 639 (Kozinski, J., concurring). Likewise, in the present case, the AG has imposed a penalty on physicians—whose only interest is their patients' well-being—to prevent patients from ending their suffering in a less painful, less prolonged manner.

Second, if the AG can unilaterally define legitimate medical practice, there is no logical basis for assuming that this power could not be extended *ad infinitum*. The AG has not advanced any limiting principle: Under its interpretation of the CSA, the AG is empowered to determine the legitimacy of any medical practice involving controlled drugs, in effect creating a new medical regulatory agency, and regulating *any* practice of medicine that involves *any* product covered by the CSA. This potentially vast authority to reach deep into the medical community has understandably concerned physicians.

Third, the Directive glosses over the significant medical issues involved in palliative care. The Directive purports to create a distinction between the "proper" distribution of pain medication and the "improper" use of medicine to hasten death. Unfortunately, the Directive's distinction is one without a difference. The practice of medicine sometimes entails the application of the doctrine of "double effect," which acknowledges the value of treating the severe pain of the terminally ill even when it is known that a consequence of that treatment may be the hastening of death.[42] As this Court noted in *Vacco v. Quill*, "[j]ust as a State may prohibit assisting suicide while permitting patients to refuse unwanted treatment, it may permit palliative care related to that refusal, which may have the foreseen but

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[42] *See* Howard Brody, *Physician-Assisted Suicide in the Courts*, 82 Minn. L. Rev. 939, 943-950 (1998).

unintended 'double effect' of hastening the patient's death." 511 U.S. at 807 n.11. In *Glucksberg*, Justice Stevens further noted that even though the American Medical Association has adopted a policy against euthanasia, it "unequivocally endorses the practice of terminal sedation—the administration of sufficient dosages of pain-killing medication to terminally ill patients to protect them from excruciating pain even when it is clear that the time of death will be advanced." *Glucksberg*, 521 U.S. at 751 (Stevens, J., concurring).[43] This widely embraced doctrine is too complex to be adequately figured into the enforcement of the CSA.[44]

Ignoring this difficulty, the Directive purports to have DEA agents second-guess physicians in an area where pain relief and death are inextricably joined. One expert has noted that the effect of the Directive will be that DEA agents "with absolutely no experience in end-of-life care will be determining if large doses of medication physicians sometimes prescribe[] to treat terminally ill patients are used with the intent of hastening death or relieving pain." Jerome Groopman, Harvard Medical School, *Separating Death from Agony*, N.Y. Times, Nov. 9, 2001, at A27.

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[43] *See also* Margaret P. Miller, *Bootstrapping Down a Slippery Slope in the Second and Ninth Circuits*, 30 Creighton L. Rev. 833, 855 (1997) ("Although some drug therapies have the 'double effect' of providing pain relief, while simultaneously hastening death, the value of the pain relief is such that the American Medical Association permits such therapy, despite its detrimental effects.").

[44] Timothy E. Quill et al., *The Rule of Double Effect*, 337 N. Engl. J. Med. 1768 (1997). In *Glucksberg*, Justice Stevens recognized the difficulty of distinguishing intent as a practical matter when, speaking of the distinction between the withdrawal of life support and assisted suicide, he noted that there might not be "a significant difference between the intent of the physicians" in these two situations. *Glucksberg*, 521 U.S. at 750.

CONCLUSION

The Directive ignores the text of the CSA and flouts deep-rooted principles of federalism. It threatens physicians and states with the loss of their long-respected right to determine the appropriate methods of medical practice and casts a pall over palliative care as physicians simply undertreat pain so as to avoid scrutiny.

The State of Oregon and people and physicians around the country have struggled in the wake of *Glucksberg* to balance competing medical, moral and public policy concerns about physician-assisted death and pain management for terminally ill individuals. They have been making progress. We therefore respectfully request the Court to affirm the decision of the Ninth Circuit.

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Dated: July 18, 2005.

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